A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RECRUITMENT OF EMPLOYEES

RECRUITING EMPLOYEES FOR AN fMRI STUDY ASSESSING THE EFFECTS OF ALCOHOL AND DRUG USE

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OVERVIEW

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:
A senior researcher and department head at a mid-size academic healthcare center is the PI of a study to test a new fMRI imaging method she hopes will provide an easy way to assess the neurobiological effects of alcohol and drug use. The researcher, a neurologist, is working with a small research team in her department and partnering with a faculty member in the department of psychology at a nearby university to review and analyze the data.

The study includes subjects who regularly smoke and drink alcohol. This group will be compared to a control group who neither smoke nor drink alcohol. Participants will be divided into the appropriate group during the screening process.

Individuals who have a drug abuse/dependence diagnosis or currently use prescribed antipsychotic, antidepressant, or other psychoactive prescription drugs, may not participate. To screen for this, the PI performs an extensive pre-screening for these criteria as well as for daily use of non-prescription drugs. A
clincian then screens prospective subjects in a formal mental health exam that includes structured clinical inventory by DSM-IV criteria (SCID). This interview asks many personal questions about emotions and behaviors and is used only as a screening tool. The consent process occurs in advance of the screening and, for those who are eligible to participate in the study, a second, shorter consent process occurs after screening.

Participants undergo the new fMRI procedure during which they are asked to perform a series of simple tasks. The session will take about two hours. All participants will be paid $35 for completing the screening and $50 for completing the fMRI session. Subjects will be paid via a check from the company that manufactures the fMRI machines. There is no direct benefit to participants.

The study received IRB approval and has been in the recruitment phase for quite some time, with low accrual. Because of the difficulty of recruiting subjects, the PI has asked, via modification at the time of continuing review, to include employees of the healthcare center as research subjects.

Questions/Comments for the researcher:
- How do you plan to recruit employees? Flyers? Email?
- Will any employees be ineligible (i.e., direct reports, colleagues, etc.)?
- How will you protect employee participant privacy and confidentiality?
- Who will perform the screenings?
- What will you do if you suspect dishonest responses during screening (regarding alcohol/drug/smoking use)?
- How will you handle incidental/ancillary findings?
- Will the data be identifiable?
- Who will have access to the data?
- How will the compensation be processed?

REGULATORY, ETHICAL, & CULTURAL ISSUES:
Vulnerable Subjects (45 CFR 46.111(b)): The IRB is required by regulation to ensure that "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects." In this study, participants who are employees would be considered a vulnerable population or a potentially vulnerable population, and added protections for privacy will be required.

Undue Influence: Will research assistants, postdoctoral trainees, or subordinates (all formally employed by the institution) feel influenced to participate in order to seek approval of their supervisor, the PI? Since the research group often works on projects with other research groups in the building and department, investigators and staff from other groups may also feel pressure to take part, as the identities of the individuals who participated will become common knowledge throughout the department.

Incidental Findings: The study team will be collecting intimate and personal information as well as health information about employees. In addition, the research may uncover incidental findings such as psychological or structural abnormalities in the course of research.
Payment: For employees who are hourly workers or non-exempt professionals, issues such as overtime might arise as an issue if the employee is not given release time from his/her supervisor. The institution employing the researchers may have policies established regarding remuneration.

Questions for the IRB:

- Has the PI sufficiently pursued other avenues for recruitment?
- Are employees being sought as a population of convenience?
- Does institutional policy allow and/or restrict the recruitment/participation of employees in research conducted at the institution?
- How does the sample size being sought compare to overall employee population? What are the implications of this ratio for the overall culture of the institution?
- What are the relationships of the researchers to the prospective (employee) subjects?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:
The assessments, tests, tasks, and scans are considered minimal risk. The MRI settings are within the required non-significant risk settings and all questions being asked are normal questions in a psychological exam, thus all study procedures are allowable under expedited review categories (Categories 3, 4, & 7), The participants will not benefit directly from the study, but there is a future potential social and scientific benefit for understanding the psychological and biomedical aspects of drug and alcohol use and abuse. The risks are reasonable in relation to the benefits.

Mitigation/Management of Risks:

Employee Recruitment & Participation:

- Employee participation requires additional privacy protections as part of the protections for a “vulnerable population.” The investigators should ensure strong privacy protections, code all the data, implement security measures to limit access to identifiable data, and store the data in password-protected files where only the PI is allowed access to the coding information.
- The consent process must include explicit statement that:
  - The decision to participate (or not) will have no bearing on employment status or performance reviews, or result in preferential treatment
  - The information collected will not affect employment or future employment
  - No materials will migrate to the employee’s employment or medical records without express authorization from the participant.
- The IRB may require an individual who is not in a supervisory position (i.e., a study coordinator or other researcher, not the PI) conduct the consent process.
- The researchers should avoid any recruitment/consent activities being done with a supervisor present and limit the number of other employees involved in the recruitment/consent/research procedures to a bare minimum so as to protect participant privacy.
• Because the possibility of undue influence exists in the recruitment of any subordinates, the IRB may choose not to allow any employees who report directly to the PI to participate, nor allow any other employees in the department to participate.

• The research should take place in a private setting with as few employees present as possible.

• Policy Solutions:

  1. Discuss with institutional officials the possibility of implementing an institutional policy that clarifies the requirements for including employees in research, and in which cases they would not be allowed to participate (i.e., avoid allowing employee participation in research that collects sensitive information).

  2. Institutional policy for non-employees (volunteers and students) should be extended to these populations because the same or similar undue influence issues could arise.

Ancillary Findings:

• While the purpose of the fMRI is not intended to be diagnostic, the licensed clinicians who perform the screening procedures have the ethical responsibility to inform a person about a potential abnormal finding.

• If abnormal ancillary findings are seen in the data, the participant should be informed of the abnormalities and told to follow up with his/her primary care doctor or another appropriate practitioner or program (i.e., a substance abuse counselor or a crisis intervention program for thoughts of suicide or self-harm behaviors).

• The clinician does not have to provide the follow-up or any counseling, but the participant needs to be informed that something suspect was found.

• The IRB may require that the participant be provided with referrals to specialists/counselors for any abnormal/concerning findings.

• Information regarding how the research team will handle incidental/ancillary findings should be provided in the consent form and explained during the consent process.

• Note: if a cognitive or structural anomaly is found during screening or data collection procedures, this may question the full legality of informed consent. (American with Disabilities act and HIPAA).

Payment of Employees:

• The investigator should check in with her institution to see if policy exists regarding research payment to employees of the institution.

• Policy Solution: Have a clear institutional policy on research payment to employees; consider alternative compensation such as gift cards.

REFERENCE(s):
45 CFR 46.111(b)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111
45 CFR 46.116
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

ADA 42 U.S.C. United States Code, 2011 Edition; Title 42 - The Public Health And Welfare; Chapter 126 - Equal Opportunity For Individuals With Disabilities
http://www2.ed.gov/about/offices/list/ocr/docs/hq9805.html

Age Discrimination act of 1975 (34 CFR Part 110)